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10/575,551	04/10/2006	Yukio Nagasaki	2006-0538A	8962

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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	PAPER NUMBER
1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,551	NAGASAKI ET AL.	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *2-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 6-11 are examined on merits. See the office action of 9/18/08 for withdrawal of claims 2-5 as being directed to non-elected invention.

Rejections Withdrawn

2. Applicant's amendments and arguments, see pp8-9, filed on March 18, 2009, with respect to the rejections under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 1 and 6-10 under 35 U.S.C. 112, second paragraph has been withdrawn in view of amendment of claims in the reply filed on March 18, 2009.

3. Applicant's amendments and arguments, see p10, filed on March 18, 2009, with respect to the rejections under 35 U.S.C. 112, first paragraph have been fully considered and are persuasive. The rejection of claims 1 and 6-10 under 35 U.S.C. 112, first paragraph has been withdrawn in view of amendment of claims in the reply filed on March 18, 2009.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites "segment of said hydrophilic polymer chain" in line 7. It is not clear what segment of hydrophilic polymer" Applicants are intended to include by the term "segment of said hydrophilic polymer chain" because different segments of a "nonionic hydrophilic polymer chain" is not clearly defined in the specification and thus the segment of the hydrophilic polymer chain intended to encompass by the term "segment of said hydrophilic polymer chain" is vague and indefinite.
7. Claim 6 provides a compound of formula (M) for "hydrophilic polymer". It is unclear whether the formula represents the "non-ionic hydrophilic polymer" or the "segment of hydrophilic polymer"? Further, X of the formula can be -COOH, which can be ionized to $-COO^-$ and thus is not non-ionic hydrophilic polymer but however, claim 1 requires "nonionic hydrophilic polymer chain".
8. Claims 7 and 8 are confusing as to the composition of the core because claim 1 from which it depends recites that the fine particle has, "as a core, a polymer chain segment with a chargeable group-carrying recurring unit" but claims 7 and 8 recites "polymer-based fine particles have, encapsulated in their core domaim, an ultrafine particle of inorganic material/semiconductor. Therefore, the composition of the core (i.e. core component) is vague an indefinite as to whether the core is composed of an ultrafine particle of inorganic material/semiconductor surrounded/encapsulated with a chargeable group carrying recurring unit (i.e. inorganic fine particle/semiconductor + chargeable group carrying recurring unit around the fine particle/semiconductor = core) or "as a core" the particle has a polymner chain segment with a chargeable group-carrying recurring unit only?

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 9, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer *et al* (US 5,750,411).

Sommer *et al* teach a method to detect an analyte in an aqueous solution with the use of an agglutination reaction of a polymer based fine particle (i.e. colloidal metal particles having polymers) comprising a) contacting fluid sample containing the analyte in a buffered aqueous system suitable for the binding of the analyte with a specific binding partner thereto, wherein the aqueous system contains colloidal sized metal particles having specific binding partner for the analyte or analyte analog bound to their surface and a polymer bearing a plurality of analyte moieties or analogs thereof covalently attached along the polymer chain which will bind to the specific binding partner bound to the metal particles to thereby form an association between the polymer and the metal particles in which the metal particles are protected by the polymer, b) adding a destabilizer material to the aqueous system which is capable of causing aggregation of the colloidal metal particle which are not protected by the polymer from the specific binding partner attached thereto to cause the metal particle which are not associated with the polymer to aggregate c) measuring the spectral properties exhibited by the colloidal metal particles at a

wavelength at which the colloidal metal particles at a wavelength at which the agreegated colloidal particles are know to absorb and d) comparing the spectral properties obtained using fluid sample having known concentrations of analyte to thereby determine the concentration of analyte in the fluid test sample (see claim 1). Sommer *et al* further teach that polymer include polyaspartic acid and polylysine (column 4, lines 6-9), which reads on chargeable group-carrying recurring unit because specification defines "chargeable" to mean that the group is charged under certain conditions, which is exemplified by -COOH, tertiary and secondary amines (page 5, lines 23-28). Polylysine polymer is also considered as non-ionic hydrophilic polymer (see claim 6).

Sommer *et al* do not specifically mention about cleaving bond made by electrostatic interaction while biologically specific bond between the fine particle is not cleaved.

However, Sommer *et al* teach that the destabilizer material can be sodium chloride (column 3, line 47), which cause dissociation of the particle and proteinaceous material by disrupting the hydrophobic or charge-charge interactions which keep the specific binding partner adsorbed to the metal particle surface (column 3, lines 41-45) and thus addition of sodium chloride increases ionic intensity (a raise of ionic intensity) of the reaction mixture which would cleave the bond by electrostatic interection but not biologically specific bond. Sommer *et al* also teach that colloidal sized metal particles tend to absorb light at one wavelength when they are in the dispersed state and at a different wavelength when the particle aggregate,

i.e. they change color and therefore (column 2, lines 61-64) and therefore, the existence of agglutinated matter after adding destabilizer is detected by a method capable of distinguishing agglomerated state and unagglomerated state.

With regard to claim 9, Sommer *et al* teach specific binding proteins such as antibody (column 3, lines 1-5).

With regard to claim 10, Sommer et al teach adding NaCl, which would raise ionic intensity of the reaction mixture.

With regard to claim 11, Sommer *et al* teach NaCl concentration of 500mM to 1M, which falls within the range of 0.1 to 2M.

11. Claims 1, 9, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Steenwinkel *et al* (US 4,362,531) in view of Stout (US 5,981,296).

de Steenwinkel *et al* disclose particle agglutination immunoassays for analyte (e.g. antigen or antibody) in a liquid sample comprising forming a mixture of the liquid sample with finely divided particles comprising a protein and a reagent, whereby specific agglutination of the particles occur to an extent dependent on the amount of analyte present and determining the said extent and thereby the amount of the analyte present, wherein the mixture also includes one or more chaotropic or chaotropic-like agents to reduce non-specific interaction (column 2, lines 59-68). De Steenwinkel *et al* disclose mixing finely divided particles bearing either an antibody or an antigen with sample liquid containing the analyte which is either an antigen or antibody, respectively. The analyte causes particles to agglutinate by simultaneous binding of two or more particles (column 4, lines 51-59). de Steenwinkel *et al* teach

that the chaotropic-like agent (e.g. sodium chloride) when used at appropriate strengths in agglutination immunoassays have the effect of reducing interference from serum proteins and this effect seems in general to be related to an increase in the ionic strength (column 3, lines 45-65; column 2, line 65 to column 3, line 3 and claim 15). de Steenwinkel *et al* further teach that chaotropic and chaotropic-like agents dissociate electrostatic and hydrophobic bonds without adverse effect on antigen antibody complex formation and thus provides substantial advantage of overcoming or reducing minor interferences (column 2, lines 42-58 and column 8, lines 52-54). de Steenwinkel *et al* disclose latex particle but teach that other types of particles can be used (column 1, lines 64-68).

de Steenwinkel *et al* do not disclose fine particle comprising polymer chain segment with a chargeable group-carrying recurring unit as a core and as plural grushes on said core or as a shell, non-ionic hydrophilic polymer chain or segment of said hydrophilic polymer chain.

Stout discloses stabilized particle for use in turbidimetric immunoassays (column 7, lines 23-26). The particle has a core covered with chargeable group carrying recurring units such as glycidyl methacrylate, glycidyl acrylate etc. (column 4, lines 5-20 and 50-58) and non-ionic hydrophilic polymer such as polyether polyamine linking group attached to the chargeable group for covalent attachment of analyte (column 5, lines 30-41). Stout teaches that the polymeric particles are resistant to premature or spontaneous aggregation during preparation and storage (column 1, lines 4-10 and column 2, lines 53-56), provides stabilized particle reagent and are

useful for analysis of a variety of materials of biological interest (column 8, lines 1-14).

Therefore, given the above fact that the polymeric particle provides stable preparation of particles and are resistant to premature aggregation, it would be obvious to one of ordinary skill in the art at the time the invention was made to consider using the polymeric particle of Stout in the method of de Steenwinkel *et al* with the expectation of improving particle agglutination immunoassay of de Steenwinkel *et al* with a reasonable expectation of success because de Steenwinkel *et al* teach that other types of particles can be used and the particles of Stout is advantageous for being able to provide stabilized preparation, resistant to premature aggregation and are useful for variety of purposes.

With regard to claim 9, de Steenwinkel *et al* disclose specific binding partner bound to particle (see claim 1) and the specific binding partner interacts with analyte in the sample and the analyte and specific binding partner comprises antigen antibody biding composition (column 4, lines 44-49).

With regard to claims 10 and 11, as described above, de Steenwinkel *et al* disclose that the use of appropriate strengths of chaotropic-like agent in agglutination immunoassays have the effect of reducing interference from serum proteins and this effect seems in general to be related to an increase in the ionic strength (column 3, lines 45-65; column 2, line 65 to column 3, line 3 and claim 15) and the optimal concentration can be obtained by routine optimization (column 3, lines 4-22). Where the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to argument

12. Applicant's arguments and mendments filed 3/18/09 have been fully considered, and are persuasive to overcome the rejections under 35 USC 112, second paragraph and 35 USC 112, first paragraph. However, a further review of the claims necessitated new ground of rejections under 35 USC 112 second paragraph and 35 USC 103, which are described in this office action.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641